

Massachusetts Department of Public Health

Project Narrative

Funding Opportunity: CDC-RFA-IP12-1206PPHF12

Program Area 5: Improve vaccine management, storage and handling at provider and grantee level

A. Background and Need Assessment

The Massachusetts Department of Public Health (MDPH) Immunization Program currently supplies over 3.2 million doses of publicly funded vaccines worth over \$120 million to over 2,500 provider sites in Massachusetts including pediatricians, family physicians, multispecialty practices, community health centers, hospitals, school and college health, and local health departments. The Program universally supplies all of the Advisory Committee on Immunization Practices (ACIP) recommended vaccines to all children thru 18 years of age regardless of their insurance status with the exception of HPV, second dose MCV4 and select adolescent catch-up vaccines which are currently only available for VFC-eligible children.

The Program has a comprehensive vaccine quality assurance plan, as outlined in the *Massachusetts Vaccine Accountability Policy*, in place to ensure the viability of the public vaccine supply in the Commonwealth. All activities are carried out through close coordination between the Program's Vaccine Management and assessment Units. This plan includes:

- Annual Enrollment of All Provider Sites: During annual VFC re-enrollment all sites agree to comply with the [*Guidelines for Compliance with Federal and State Vaccine Administration Requirements*](#) which is a comprehensive 12-page document outlining all the minimum requirements for vaccine storage and handling and VFC program compliance. These Guidelines are based on the CDC's Vaccine Storage and Handling Guide and VFC Operations Manual.

- **Reduce Excess Inventories at Provider Sites:** Providers are required to report doses used, current inventory, doses lost/expired with each vaccine order. This data is analyzed during the order approval process and vaccine orders are reduced and sites are followed up with if orders exceed internal guidelines for maximum allowable inventories.
- **Ensure Vaccines Are Being Stored Appropriately:** All pediatric provider sites are supplied with certified, calibrated product temperature thermometers. Providers are required to submit temperature logs with each vaccine order. The temperature logs must include at a minimum twice a day vaccine temperature recordings. These logs are reviewed and any out of range temperatures are referred to the Vaccine Manager or VFC Coordinator for follow up. Providers are also instructed to call the Vaccine Management Unit whenever there is a temperature variation outside the recommended storage range.
- **Verify that Vaccines Are Being Administered to the Appropriate Age Groups:** Providers are required to report vaccine usage by age group with each vaccine order. This data is analyzed to ensure doses are administered to the appropriate ages.
- **Maintain Vaccine Waste at Less than 3% of Vaccine Doses Distributed:** Sites reporting any amount of expired vaccine are counseled to redistribute vaccines to another site before expiration, or restitution in the form of replacement doses will be required.
- **Prevent, Identify, or Document Instances of Fraud or Abuse:** The Program has a detailed VFC Fraud and Abuse Policy that is updated jointly with the Commonwealth's Medicaid office. The Program works closely with the state Medicaid program on any suspected incidents of VFC fraud and abuse.
- **Restitution Policy:** The Program seeks restitution in the form of replacement doses when providers misuse vaccine, or waste vaccine due to negligence if it is the first incident and

the total loss is over \$10,000, or the second incident (or greater) – regardless of total value, or due to a failure to immediately open a vaccine shipment from McKesson or Merck resulting in damaged vaccine, regardless of total value. Providers are suspended from ordering vaccines until documentation is sent showing that restitution was made. Restitution can include purchase of new vaccine storage units or temperature monitoring devices in lieu of replacement vaccine.

- Provider Training and Resources: *Immunization Update* workshops are held at six locations throughout the state each spring, and an on-line webinar is produced for sites that cannot send staff.
- VFC Site Visits: Enrolled, active, pediatric providers receive a VFC site visit every other year. During the visit, the complete VFC Site Visit Questionnaire is administered. A Corrective Action Plan is required to be returned by sites if any issues are identified during the site visit. If any issues identified are significant, or the number of issues is great, the site will be enrolled in follow-up activities. Routine, secondary, or tertiary follow-up may be used, depending on the situation (following CDC's *Non-Compliance with VFC Provider Requirements Algorithm*). Follow-up activities include phone calls, emails, faxes and visits to the practice to ensure changes are implemented to bring the practice into compliance with VFC Program requirements.

Despite the comprehensive plan outlined above there are still some significant gaps in vaccine storage and handling practices at provider offices both nationally as identified in the recent Office of the Inspector General report and in Massachusetts. In 2011, out of 519 sites in Massachusetts receiving a VFC site visit:

- 12% (n=62) had temperatures out of range at some point during the last three months on their temperature logs;
- 3% (n=16) had temperatures out of range the day of the assessment;
- 2% (n=12) were not recording temperatures twice daily;
- 4% (n=22) were using a dormitory-style refrigerator (for secondary or temporary vaccine storage).

In addition to the provider site visits, out of range temperatures are also discovered during the routine review of temperature logs submitted with monthly vaccine orders. In 2011, six sites were identified to have out of range temperatures using this methodology and 13 sites were identified in 2010. All sites identified with significant vaccine storage issues that may require revaccination are sent written guidance from the Vaccine Unit and the Medical Director.

Based on these findings there are two primary areas of concern where MDPH would like to implement a plan to improve provider vaccine storage and handling practices even further:

1) dormitory-style refrigerators - currently MDPH does not allow the use of dormitory-style refrigerators for the primary vaccine storage unit at a provider site; however, as allowed by CDC, the Program does allow dormitory style units for temporary vaccine storage; 2) the current practice of recording temperatures only twice daily and reporting of the temperatures only once a month to the Program. Outlined below is our plan to improve the current practices in these two areas.

B. Implementation Plan

This grant opportunity will enable the MDPH to specifically address the two areas identified above in the Needs Assessment. With implementation of this grant, MDPH will embark on an enhanced provider education campaign focused on vaccine storage and handling practices. One

core component of this campaign will be the implementation of a new policy to no longer allow the use of dormitory-style refrigerators for any vaccine storage use (whether permanent or temporary). Sites will be educated about the inadequacy of dormitory-style units and will be given enhanced guidance on the types of refrigeration units that are recommended for vaccine storage. This educational campaign will be multifaceted and will include:

- printed materials to be distributed during VFC site visits, at conferences, Grand Round presentations, and by vaccine manufacturer representatives;
- information posted on the MDPH and Massachusetts Chapter of the American Academy of Pediatrics websites;
- routine email alerts to all providers on the MDPH Vaccine Unit's list serve;
- integration into presentations given at annual Immunization Updates, annual pediatric and adult immunization conferences, MCAAP-sponsored Grand Rounds presentations, and trainings provided to internal MDPH staff;
- webinars to be developed and hosted throughout the year and then published online for future viewing; and
- newsletter articles disseminated to providers by MDPH's partner organizations including the MCAAP, state Medicaid program, large provider networks, private health plans, and the Massachusetts League of Community Health Centers.

This grant opportunity will also enable the MDPH to improve the current active reporting process for vaccine temperatures. Funds will be used to purchase National Institute of Standards and Technology (NIST) certified calibrated digital product temperature thermometers with continuous data logging and wireless data communication capabilities. These units will be provided to the top 500 practices in the state for use in their primary vaccine storage unit. Many

of the largest practices in the state (primarily hospitals and large multi-specialty group practices) have already implemented similar temperature monitoring systems. A survey will be done to evaluate the monitoring systems of these sites to ensure they are in compliance with minimum MDPH standards (NIST certified thermometers, measurement of product temperatures, continuous data logging with data download capabilities) and if sites already have acceptable temperature monitoring systems in place they will be excluded from the list of sites to be supplied these new monitoring units, enabling even more sites to be covered by the new temperature monitoring units. These units will have at a minimum the capability to send data electronically directly to the health care provider site and to the MDPH. Software development work will be done to allow for the data to be downloaded directly into the Massachusetts Immunization Information System (MIIS) for easy viewing, monitoring, and future reference by both provider staff and MDPH staff.

For smaller sites that will not be selected to receive these new digital temperature data loggers, additional enhancements will be made to the vaccine management module of the MIIS to allow for electronic uploading of scanned monthly temperature logs, as opposed to the current practice of faxing the temperature logs. There will also be additional development work to create a new user interface screen for the manual input of temperatures directly into the MIIS. This will allow sites the ability to record their twice daily temperatures directly in the MIIS which would give MDPH real time visibility into vaccine temperatures being recorded at provider offices. Both of these enhancements to the MIIS will be worked on in the fall of 2012 through the winter of 2013 with an anticipated release of the new functionality in later summer or early fall 2013.

This grant will also provide funding for an epidemiologist to make enhancements to the current in-house developed Access database which stores all the VFC provider site visit data.

Enhancements to the database will allow for enhanced data analysis and report functionality and will aid in improving and enhancing current VFC-site visit follow-up activities. The contract epidemiologist will also enhance the currently tertiary follow-up activities performed by the MDPH Assessment Unit by working directly with provider sites receiving tertiary education as a result of deficiencies identified during the VFC provider site visit.

1. Timeline

The enhanced educational campaign will begin in early 2013 and will last for 12 months with a deadline of January 1, 2014 for all sites to be in compliance with the new requirement to not use any dormitory-style refrigerators for vaccine storage. Sites identified as having such units during the 2012 and 2013 VFC provider site visits will be required to attest in writing that they no longer are using any dormitory-style refrigerators by January 1, 2014 or they will be suspended from receiving any state-supplied vaccines.

Enhancement of the active reporting of vaccine temperatures will occur primarily in 2013. In the fall of 2012 the new data loggers will be procured with plans for dissemination of the units and training on their use to occur throughout 2013 with a goal of having them all fully installed and operational by January 1, 2014. Development work for the MIIS interface will occur in early 2013 with the goal of integrating in a future release of the MIIS to be rolled out in late summer/early fall 2014.

2. Evaluation and Objectives

Please note that the timelines below assume a grant award date of September 1, 2012.

Objective 1: An enhanced vaccine storage and handling provider education campaign will be implemented in 2013. The following table presents the activities, timeline, evaluation and staffing plan that will be utilized to implement and achieve this objective:

Activities	Timeline	Evaluation Measures	Staffing Plan
Development of new printed materials and web resources.	October 2012-February 2013	Completion of newly developed materials and resources	Pejman Talebian, Bob Morrison, MCAAP, and JSI
Posting of new materials and information on the web.	March 2013	New information and materials posted on the MDPH and MCAAP websites	Pejman Talebian and MCAAP
Development and rollout of webinars.	January 2013-December 2013	Implementation of webinars with at least 200 provider sites participating	Pejman Talebian, Bob Morrison, MCAAP, and JSI
Integration of new information in presentations.	January 2013-August 2014	Inclusion of enhanced messaging around vaccine storage and handling in the 2013 and 2014 Immunization Updates, MCAAP Grand Rounds, and MIAP annual conferences.	Pejman Talebian, Bob Morrison, MCAAP, and JSI
Publication of newsletter articles by partner organizations.	January 2013-August 2014	Publication of at least one newsletter article in the MCAAP, Medicaid, and Mass League of CHCs newsletters.	Pejman Talebian and MCAAP

Objective 2: Active reporting of vaccine temperatures will be enhanced in all pediatric provider offices by early 2014. The following table presents the activities, timeline, evaluation and staffing plan that will be utilized to implement and achieve this objective:

Activities	Timeline	Evaluation Measures	Staffing Plan
Purchase NIST certified calibrated digital product temperature thermometers with continuous data logging and wireless data communication	September 2012- December 2012	Successful procurement of 500 vaccine temperature data loggers meeting all the required specifications	Pejman Talebian and Bob Morrison
Conduct a survey of the top pediatric practices in the state to evaluate the current vaccine temperature monitoring systems in place.	September 2013- October 2013	Responses received from at least 50% of the top 200 practices in the state.	Pejman Talebian, Bob Morrison and Lois Ciccone
Distribute, install and train on the use of the new digital data loggers at the top 500 pediatric practices in the state that currently do not have similar capabilities.	January 2013- December 2013	Successful install and training of all new data logger units purchased at all 500 locations.	Pejman Talebian, Bob Morrison, Lois Ciccone, Kathleen Shattuck, Beth English
Develop a new user interface within the MIIS vaccine management module to	October 2012- August 2013	New MIIS enhancements fully implemented and in production by fall	Pejman Talebian, Bob Morrison, Doreen Corban, Saravana Kannan

Activities	Timeline	Evaluation Measures	Staffing Plan
allow for enhanced vaccine temperature reporting.		2013.	
Roll out and train providers on the use of the new enhanced vaccine management module.	September 2013- August 2014	At least 75% of all pediatric provider sites utilizing the enhanced vaccine temperature reporting capabilities of the MIIS summer 2014.	Pejman Talebian, Beth English, Liesl Bradford
Go live with daily temperature reporting from the top 500 pediatric practices in the state.	September 2013- August 2014	Receipt of daily temperatures from the top 500 pediatric practices in the state.	Pejman Talebian, Bob Morrison, Beth English, Liesl Bradford

Objective 3: The use of dormitory-style refrigerators for storage of any publicly-funded vaccines will no longer be permitted as of January 1, 2014. The following table presents the activities, timeline, evaluation and staffing plan that will be utilized to implement and achieve this objective:

Activities	Timeline	Evaluation Measures	Staffing Plan
Information about new policy will be integrated into the new enhanced information campaign.	October 2012- March 213	Successful inclusion of new information in all materials and resources	Pejman Talebian, Bob Morrison, MCAAP, and JSI
Communications sent out to all provider sites	January 2013 – December 2013	At least 4 alerts will be sent to all provider	Bob Morrison and Lois Ciccone

Activities	Timeline	Evaluation Measures	Staffing Plan
on the upcoming new requirement.		sites during 2013 regarding the new requirement. Also will be included in the 2014 VFC enrollment agreement.	
Data analysis will be done on the 2012 and 2013 site visits to identify sites that still use dormitory style refrigerators.	February 2013- January 2014	Availability of data to identify sites that may not be in compliance with the updated policy to be in effect January 1, 2014.	Kathleen Shattuck
Letters will be sent to all sites identified as still using dormitory-style units (as identified above) with a requirement for them to sign a statement attesting to the replacement of such units.	July 2013- December 2013	Mailing of letters by July 2013 for sites identified as deficient during 2012 site visits and by December 2013 for sites identified as deficient during 2013 site visits.	Bob Morrison and Lois Ciccone
All sites that have not confirmed the decommissioning of their used dormitory-style refrigerators will be suspended from vaccine ordering.	January 2014	Number of sites that are suspended from ordering vaccines.	Bob Morrison and Lois Ciccone

Objective 4: The incidents of out of range temperatures as identified during provider site visits will reduced by at least 50% by 2014. The following table presents the activities, timeline, evaluation and staffing plan that will be utilized to implement and achieve this objective:

Activities	Timeline	Evaluation Measures	Staffing Plan
Enhancements to the assessment database allowing for more detailed data analysis and report will be implemented.	December 2013-June 2013	Ability to run reports and detailed data analysis from the assessment database	Kathleen Shattuck, Monica Morrison
Enhanced tertiary follow-up activities will be performed on provider sites with significant vaccine storage and handling practices identified.	July 2013-June 2014	The number and frequency of contacts with sites enrolled in tertiary follow-up will increase by 50%.	Kathleen Shattuck, Monica Morrison
Data analysis will be performed on the 2012, 2013, and 2014 VFC provider site data.	January 2013-December 2014	Availability of detailed data analysis of VFC provider site visit information which will be used for enhanced tertiary follow-up.	Kathleen Shattuck, Monica Morrison

3. Justification for the number of VFC providers

Massachusetts has over 2,500 provider sites who receive state-supplied vaccines with over 1,400 enrolled in the VFC program. The enhanced educational campaign will be provided to all

provider sites with a focus on those enrolled in the VFC program. As outlined above, the enhanced active reporting of vaccine temperatures will be targeted to the top 500 practices which will enable close to real time continuous monitoring of vaccine temperatures by MDPH of over 93% of the publicly-funded vaccine supply in the Commonwealth worth over \$111 million.

C. Capacity

As outlined in the Budget Justification, this grant will support the addition of 1.5 full time MIIS User Support Staff hired through a contract with John Snow Inc. (JSI). MDPH currently has a contract with JSI for MIIS user support and roll out activities; therefore, this additional funding will supplement the existing contract. The grant will also support one full time IT Systems Analyst hired through a contract with Strategic Solutions Group (SSG). MDPH currently has a contract with SSG for IT project management, IT systems development and QA; therefore, this additional funding will supplement the existing contract. The grant will also support the addition of a full time Epidemiologist hired through an existing contract with Resource Connection to help support enhanced data analysis, database enhancements and follow-up activities within the MDPH Assessment Unit during the transition to the new vaccine ordering system. The grant will also support enhancement of currently provider education activities preformed by the Massachusetts Chapter of the American Academy of Pediatrics (MCAAP). MDPH currently has a contract with the MCAAP who has been the primary external partner organization that the MDPH has utilized for over 20 years to provide health education to pediatric primary care providers in the Commonwealth. In addition to the new staff supported by this grant, existing staff will provide overall project management, technical expertise, and support for all activities outlined in this application.

The following individuals and teams providing support and oversight to this project:

1. Dr. Susan Lett, Medical Director and Program Manager, Immunization Program.

Susan M. Lett, MD, MPH has been the medical director of the immunization program at the Massachusetts Department of Public Health for 24 years and the program manager for over 10 of those years. She is a former member of the both the Advisory Committee on Immunization Practices (ACIP) and the National Vaccine Advisory Committee (NVAC). She has written many articles and given numerous presentations about immunizations.

2. Operations and Planning Team. Led by Pejman Talebian, Deputy Director for Policy and Planning and Beth English, Deputy Director for Operations. Pejman Talebian has over 14 years of state immunization program management experience and has worked on immunization policy and planning on both the state and national level. He is a former Chair of the Association of Immunization Managers (AIM), current member of the AIM Executive Committee and current co-chair of the AIM Vaccine Storage and Handling workgroup. Beth English has extensive experience in contract management, budget development and monitoring, and state and federal reporting.

3. Vaccine Management Unit. Lead by Robert Morrison, Vaccine Manager. Robert Morrison has been the MDPH Immunization Program Vaccine Manager for the past 17 years. As part of his responsibilities, Bob manages a \$120 million vaccine budget and over 3.2 million doses of vaccine distributed annually to over 2,500 provider sites. He supervises all staff within the Unit which is responsible for processing approximately 12,000 vaccine orders and responding to an estimated 20,000 phone calls annually.

4. Assessment Unit. Lead by Kathleen Shattuck, Assessment Coordinator. Kathleen has worked for the Immunization Program for six years. For the last four years, Kathleen has led the Assessment Unit, supervising two epidemiologists and six research analysts. In addition to

conducting hundreds of annual provider site visits and trainings annually, Assessment Unit staff track, analyze and report on the data collected.

5. **Registry User Support Unit.** Led by Beth English, Deputy Director for Operations and Liesl Bradford, MIIS Roll-Out Coordinator. Liesl Bradford's technical expertise includes program design, implementation, management and evaluation, technical assistance, online and database management, and training curriculum development. Liesl Bradford and Beth English are responsible for the coordination of the roll-out of the MIIS to all healthcare provider sites and supervising the User Support Team who assists in rolling out the MIIS to all providers in MA, provides technical assistance to end users and serves as front-line resource to providers.

6. **Doreen Corban, Director of IT, Bureau of Infectious Diseases.** In managing all IT infrastructure and projects for the Bureau of Infectious Disease, Doreen Corban coordinates the efforts of the MIIS with other similar projects. Her extensive experience in managing IT teams and budgets, establishing system development lifecycles, and cross-functional knowledge of public health systems ensure success of the IT implementation and provides strong leadership for the IT team.

7. **MIIS Development Team.** The Development team is a proven and experienced team specializing in J2EE applications and HL7 standard messaging. The IT architecture leverages robust platform tools, including IBM WTX, and follows industry standard design practices for Services Oriented Architectures, including appropriate separation of application layers and loosely coupled, web service based system interfaces.